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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/509,934	05/03/2000	ANDREAS STEINMEYER	SCH1747	6707
7590 02/10/2006 MILLEN WHITE ZELANO &BRANIGAN ARLINGTON COURTHOUSE PLAZA I 2200 CLARENDON BOULEVARD SUITE 1400 ARLINGTON, VA 22201			EXAMINER QAZI, SABIHA NAIM	
			ART UNIT 1616	PAPER NUMBER
DATE MAILED: 02/10/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/509,934	STEINMEYER ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Sabiha Qazi	1616	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 16 November 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-3,5,6,14,19,21-26,28-36,38 and 40-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 1-3,5,6,14,19,21-26,28-36,38 and 40-45 is/are allowed.
- 6) ☐ Claim(s) 46-48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

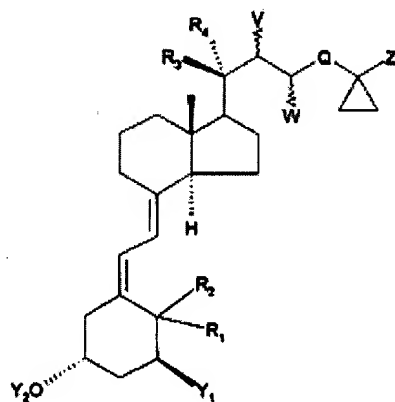
- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

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**Non Final Office Action**

Acknowledgement is made of the amendments filed on 11/16/05. Amendments are entered. Claims 1-3, 5, 6, 14, 19, 21-26, 28-36, 38, 40-48 are pending. Claims 1-3, 5, 6, 14, 19, 21-26, 28-36, 38, 40-45 are allowed. Claims 46-48 are rejected.

Instant claims are drawn to vitamin D compounds of formula (I), in claim 1, where R<sub>1</sub> and R<sub>2</sub> can be exocyclic methylene group, Z represents OH, R<sub>3</sub> can be CH<sub>3</sub>, R<sub>4</sub> can be H, V is OH and W is H or together may form a double bond, and Q is straight or branched hydrocarbon which can be substituted by OH at any position.



(I) of present

invention.

**Response to Arguments**

- Claims are amended therefore the rejection is withdrawn.
- Upon further review of prosecution history it was found that new claims 46-48 contain a proviso, which is considered a negative limitation.

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- In order to advance the prosecution Applicant may consider calling the Examiner to discuss the issues surrounding this application.
- Examiner thanks Attorney Brion P. Heaney for his cooperation during the prosecution of this application.
- Applicant is requested to disclose the prior art, which has been disclaimed by the proviso in claim 46.

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 46-48 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The proviso in claim 46 that “Q is not either –CHOH or CHOH in which the OH group is esterified” is considered a “new matter”

- MPEP 2173.05(i) states: “Any negative limitation or exclusionary proviso must have basis in the original disclosure. See *In re Johnson*, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977). See *Ex parte Grasselli*, 231 USPQ 393 (Bd. App. 1983), *aff’d mem.*, 738 F.2d 453 (Fed. Cir. 1984). Any claim containing a

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negative limitation, which does not have basis in the original disclosure, should be rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement.

- The instant claims 46-48 therefore are rejected under 35 U.S.C. 112, first paragraph, under instruction from MPEP 2173.05(i), because they contain a negative limitation that does not have basis in the original disclosure.
- In *Purdue Pharma LP v Faulding, Inc.*, 230 F.3d 1320, 1326, 56 USPQ2d 1481, 1486 (Fed. Cir. 2000), the court noted that with respect to *In re Ruschig*, 371 F.2d 990, 154 USPQ 118 (CCPA 1967),
- “Ruschig makes clear that one cannot disclose a forest in the original application, and then later pick out a tree of the forest and say, “here is my invention”. In order to satisfy the written description requirement, the blaze marks directing the skilled artisan to that tree must be in the originally filed disclosure.”
- In *In re Johnson*, the court noted that any negative limitation or exclusionary proviso *must have basis in the original disclosure*. Only if alternative elements are positively recited in the specification, they may be explicitly excluded in the claims. In the present case the negative limitation/exclusionary proviso does not have basis in the original disclosure, and the alternative elements were not positively recited in the specification.
- *Purdue* is relevant in this case, because the Appellants disclosed a genus (“a forest”) in the original application, then later picked out two specific compounds (“a tree of the forest”), and are now saying, “here is my invention”. In order to

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satisfy the written description requirement, according to *Purdue*, the Appellants must disclose the specific compounds in the originally filed disclosure.” (See (56 USPQ2D 1481).

- More from *Purdue*: The case of *In re Ruschig*, 379 F.2d 990, 154 USPQ 118 (CCPA 1967), is instructive here (see page 1487). The claim at issue in that case was directed to a single compound. The appellants argued that, although the compound itself was not disclosed, one skilled in the art would find support for the claimed compound in the general disclosure of the genus of compounds to which the claimed compound belonged. The *Ruschig* court rejected that argument, stating: [i]t is an old custom in the woods to mark trails by making blaze marks on the trees. It is of no help in finding a trail or in finding one's way through the woods where the trails have disappeared-or have not yet been made, which is more like the case here-to be confronted simply by a large number of unmarked trees. We are looking for blaze marks, which single out particular trees. We see none. *Id.* at 994-95, 154 USPQ at 122.
- Examiner believes that since the proviso that “Q is not either –CHOH or CHOH in which the OH group is esterified” were not specifically disclosed in the specification or in original claims, disclaimer in claim 46 containing a negative limitation to exclude these compounds, does not have basis in the original disclosure, and should be rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement.

**Contact Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi whose telephone number is (571) 272-0622. The examiner can normally be reached on any business day.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Padmanabhan, Sreeni (acting) can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Saturday, February 06, 2006



SABIHA QAZI, PH.D  
PRIMARY EXAMINER